UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION NUMBER: 19-md-02875-RBK-JS**
	TELEPHONIC ORAL ARGUMENT AND ORAL OPINION AND RULINGS ON MACRO DISCOVERY DISPUTES BETWEEN PLAINTIFFS AND THE WHOLESALER AND RETAILER/PHARMACY DEFENDANTS [DOCKET NOS. 413, 478, 479, 501, 503]

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
July 06, 2020
Commencing at 1:30 p.m.

B E F O R E: **THE HONORABLE JOEL SCHNEIDER, UNITED STATES MAGISTRATE JUDGE**

A P P E A R A N C E S:

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
For the Plaintiffs

GOLOMB & HONIK, P.C.
BY: RUBEN HONIK, ESQUIRE
BY: DAVID J. STANOCH, ESQUIRE
1835 Market Street, Suite 2900
Philadelphia, Pennsylvania 19103
For the Plaintiffs

Carol Farrell, Official Court Reporter
cfarrell.crr@gmail.com
856-318-6100

Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

A P P E A R A N C E S (Continued):

KANNER & WHITELEY, LLC
BY: CONLEE S. WHITELEY, ESQUIRE
701 Camp Street
New Orleans, Louisiana 70130
For the Plaintiffs

DUANE MORRIS LLP
BY: SETH A. GOLDBERG, ESQUIRE
30 South 17th Street
Philadelphia, Pennsylvania 19103
For the Defendants, Walmart, Prinston Pharmaceuticals, Solco Healthcare U.S. LLC, and Zhejiang Huahai Pharmaceuticals Ltd.

BARNES & THORNBURG LLP
BY: SARAH JOHNSTON, ESQUIRE
BY: KRISTEN L. RICHER, ESQUIRE
2029 Century Park East, Suite 300
Los Angeles, CA 90067
For the Retailer Defendants and CVS Pharmacy

NORTON ROSE FULBRIGHT US LLP
BY: D'LESLI M. DAVIS, ESQUIRE
1301 Avenue of the Americas
New York, New York 10019
For the Defendant, McKesson

ULMER & BERNE LLLP
BY: JEFFREY D. GEOPPINGER, ESQUIRE
600 Vine Street, Suite 2800
Cincinnati, Ohio 45202
For the Defendant, AmerisourceBergen

(PROCEEDINGS held via teleconference before The Honorable Joel Schneider, United States Magistrate Judge, at 1:30 p.m.)

THE COURT: This is Judge Schneider. We are on the record in the Valsartan MDL, Docket Number 19-2875.

When I called in to this conference call, 40 people apparently are on the line. I don't think we need to get appearances from everyone who is on the line unless they want to, but, certainly, we should get appearances from leadership counsel, from the parties, and whoever is going to speak today. And whoever is going to speak, as usual, please state your name so the court reporter knows who's talking.

Start with plaintiffs.

MR. SLATER: Hello, your Honor. Adam Slater for plaintiffs.

MR. HONIK: Good afternoon, your Honor. Ruben Honik for plaintiffs.

MS. WHITELEY: Good afternoon, your Honor. Conlee Whiteley for plaintiffs.

THE COURT: Defendants?

MR. GEOPPINGER: Good afternoon, your Honor. Jeff Geoppinger, G-E-O-P-P-I-N-G-E-R, for AmerisourceBergen.

MS. JOHNSTON: And good afternoon, Your Honor. Sarah Johnston for the retailer defendants and CVS Pharmacy.

MS. DAVIS: Your Honor, this is D'Lesli, D-apostrophe-L-E-S-L-I, Davis, for McKesson, and speaking as

point today for the defendant wholesalers.

THE COURT: Does anyone else want to put their appearances on the record?

MR. GOLDBERG: Your Honor, this is Seth Goldberg. I'm on in my capacity as counsel for Walmart and, to the extent necessary, I may speak on behalf of Walmart.

MR. STANOCH: Judge, this is David Stanoch, S-T-A-N-O-C-H. I may speak at parts for plaintiffs.

MS. RICHER: And, your Honor, this is Kristen Richer with Barnes & Thornburg, also on behalf of the retailers and CVS. I may speak as to a few brief issues.

THE COURT: Does anyone else want to put their appearances on the record now?

(No response.)

THE COURT: Thank you.

The Court has received all the parties' briefs and has read them, as well as the accompanying exhibits and declarations. Before we get into the oral argument on the discovery issues in dispute, there's just a couple of background questions that I have that I just wanted to clarify.

Attached to Mr. Slater's April 13th letter as Exhibits B and C are the requests for production of documents directed to the wholesaler group and the retailer/pharmacy group. Are those the documents that these discovery disputes

arise out of?

MR. STANOCH: Your Honor, this is David Stanoch for plaintiffs.

The answer to that is yes, they are. There may have been a few subsequent tweaks to the one with the retail pharmacy defendants per meet-and-confer discussions, but for purposes of today's call, I think the answer is yes, your Honor can have Exhibits B and C in front of you, as necessary.

MS. DAVIS: Your Honor, D'Lesli Davis for the wholesalers. That is correct, for wholesalers.

MS. JOHNSTON: And yes, your Honor, for the retailer defendants, Sarah Johnston. I agree with Mr. Stanoch's representation. There have been some changes to some of the language, but nothing that would affect the arguments today.

THE COURT: So the issues that have been identified in the letter briefs the Court received, it's the Court's understanding that those are the only disputes that remain to be decided before those requests for production are finalized. Am I right?

MR. STANOCH: That would be -- this is David Stanoch again, your Honor.

That would be plaintiffs' position, yes.

MS. DAVIS: Your Honor, D'Lesli Davis for the wholesalers.

I believe that's correct; of course, assuming that

the draft that you're looking at is what comes from the plaintiffs' ultimately, and with the note that the plaintiffs are the ones who identified, you know, the issues that they felt should be fought over as macro issues.

MS. JOHNSTON: And, your Honor, Sarah Johnston for the retailers.

We've been working to, as I said, clean up a few remaining issues. And the final set of requests will need to be revised to reflect the Court's rulings today.

THE COURT: All right. So let me just put this in perspective because I want to be clear on this.

With regard to the manufacturer defendants, we have already entered a set of Court-approved document requests. Am I correct that the fact sheets to the manufacturers need to be finalized?

MR. STANOCH: Your Honor, David Stanoch again.

I believe that is correct, on both counts.

THE COURT: With regard to the two groups we're dealing with today, the wholesalers and the retailers -- when I say retailers, that includes the pharmacies -- is my understanding correct that the parties have either explicitly or implicitly agreed that these groups of defendants are just going to respond to the requests for production and not separate fact sheets or am I wrong about that?

MR. STANOCH: Your Honor, David Stanoch for

plaintiffs again.

I think that's not correct, your Honor. I think it is the intention for the document requests for both of these downstream defendant groups to be finalized and responded to, and then, in short order, the parties finalize the defendant fact sheets for each group as well.

THE COURT: What is the status of the discussion regarding the fact sheets to be answered by these two groups of defendants? Because I recall entering an order saying that we have this group answering first, then 60 days, another group, and then 60 days, another group. So what's the status of the fact sheets directed to the wholesalers and retailers?

MR. STANOCH: Your Honor, David Stanoch for plaintiffs -- plaintiffs again.

I believe there has been some ongoing discussions with the retail pharmacy defendants. I think any discussions are stalled or delayed, pending the ruling on these macro issues with the wholesaler defendants. But I think it is our view that we want any fact sheet issues with both groups to be teed up, I believe your Honor said, by the end of July, unless I'm mistaken, so that those facts -- all the fact sheets can be resolved by then.

THE COURT: All right --

MS. JOHNSTON: Your Honor, Sarah Johnston for the retailers.

The discussion of the fact sheets was tabled at the recommendation of plaintiffs while we were waiting on the Court's decision on the macro issues.

So I think that the last set of revisions to the DFS were sent to plaintiffs maybe six or eight weeks ago. But we have tabled those discussions, so we would need to pick those back up, depending on how things go today.

THE COURT: What is going to be addressed in the fact sheets that is not going to be addressed in the requests for production directed to these two groups?

MR. STANOCH: Your Honor, David Stanoch.

I believe the requests we're talking about today are sort of globally, litigation-wide, the documents and data the plaintiffs are seeking, whereas the fact sheets to these groups of defendants would be individual plaintiff-specific-type questions, to the extent the data is available, for those defendants to say, for example, which particular valsartan products that individual plaintiffs might have bought.

MS. JOHNSTON: Your Honor, for the retailers.

This is primarily going to be records like dispensing records for an individual plaintiff, at least on the pharmacy side.

THE COURT: And I think that will be affected by, I think, the Court order where it indicated the number of

consumers whose records have to be searched. Am I right about that?

MR. STANOCH: David Stanoch.

Yes, your Honor, I think that's correct.

THE COURT: Okay. Understood.

So if we decide these issues that we're going to be presented with today in short order, these document requests can be finalized, and shortly after that, we'll finalize the fact sheets for these two groups, and once they're entered, that will trigger 60 days to respond, 60 days to respond, 60 days to respond.

Just to tie the knot, finish the knot, what is the status of the discussions of the fact sheets, finalizing the fact sheets with the manufacturers?

MR. GOLDBERG: Your Honor, this is Seth Goldberg, and I'll jump in on behalf of ZHP at this point.

I do know that my colleague, Barbara Schwartz, has been in discussions with Marlene Goldenberg, counsel for plaintiffs, to get that finalized. I expect it's close to being done.

THE COURT: Fair enough.

All right. Turning to another --

MR. GOLDBERG: Your Honor, before you go -- yeah, I'm sorry. This is Seth Goldberg again on behalf of Walmart.

And before you go on, I just wanted to clarify one

thing about what your Honor has said with respect to finalizing the retailer document requests.

Walmart does have an issue with respect to two of their requests, just two, and we're hoping to work through that with plaintiffs and -- over the next week or two, and, hopefully, can meet and confer with plaintiffs. We have invited plaintiffs to do that. So I just want to be clear that, at least for Walmart, there is a specific dispute as to two requests.

THE COURT: Mr. Goldberg, let me tell you the Court's position because this was raised in one of Mr. Slater's letters. We are finalizing these requests for production hopefully today, but no later than Thursday.

As far as the Court is concerned, the only disputes remaining are those disputes in the letters that the Court received. The Court will not address any other issue other than the issues that have been raised in the letters submitted to the Court. It was represented in those letters that those were the only disputes remaining with regard to the requests for production.

The Court is not going to address individual objections by individual retailers and wholesalers. They had the opportunity to raise those issues. The time has passed, and the Court will only address the issues in the letters. There is not going to be weeks of meet and confer on this. I

expect to enter these requests for production either Thursday or no later than Friday.

MR. GOLDBERG: Yes, I understand. I understand, your Honor. I don't mean to say there is an objection to the requests as much as how Walmart envisions responding to two of the requests, and that is an issue that we intend to meet and confer with plaintiffs on. And I don't want to derail this, you know, your Honor getting to the macro issues, but maybe it's something we can pick up after the macro issues. But there are two -- there are two requests that do create a significant and demonstrable burden on Walmart, and Walmart would like the opportunity to meet and confer with plaintiffs about a potential compromise to alleviate that burden.

THE COURT: If you could work it out with plaintiffs, that's fine. You have until Thursday. I said what I said. It was represented to the Court that the only remaining disputes are those in the letters, and those are the only issues the Court is going to address.

Let's get to the letters. I'd like to start by just framing the issues in dispute, and we'll deal with one issue at a time.

The first issue that I would like to address is -- these are my words -- this tracing issue involving the wholesaler defendants. And I want to make sure before we get into the argument that we all use a consistent terminology,

and we know what we're arguing about.

As I understand the issue, plaintiffs, in effect, you're asking the wholesalers to produce, during the relevant time period, all of the information that they receive from their upstream supplier, whether it was a manufacturer or the finished dose manufacturer, and then you're asking the wholesalers to produce all information that was provided to the pharmacies, or that documents for sales -- I said pharmacy. I meant retailers. And that's the Court's understanding of what this tracing dispute is. Am I phrasing it correctly?

MR. STANOCH: Your Honor, David Stanoch for plaintiffs.

Yes, I think that's a fair characterization.

MS. DAVIS: Judge, this is D'Lesli Davis for the wholesalers.

I think, generally speaking, as we've had our meet and confers, that's correct.

The specific language of the request, though -- and this goes to both upstream and downstream -- is documents sufficient to identify date of purchase or sale, quantities of purchase or sale, NDC number, lot number, and expiration date. And then there are two caveats: To the extent you maintain that in your ordinary course of business, and to the extent it can be collected by a reasonable search. So maybe it's a

little narrower than what you say, and, of course, the wholesalers would say that the course of business way that it is maintained in a trustworthy manner -- and that could be done by a search. I'm not sure we're ready to concede it's reasonable -- would be the output through that exemplar that we showed you. And that does not include lot or expiration date information, certainly, all the way downstream to retailer.

THE COURT: I want to be clear on this because it will work to avoid confusion and a dispute in the future. If plaintiff said give me all the information -- I'm trying to phrase it so that there is no misunderstanding about what we're talking about.

When the manufacturers supply the wholesalers, when they sell the wholesalers' product, valsartan-containing drug, plaintiffs want all the documents that will memorialize that transaction. Is that your understanding of what they want?

MS. DAVIS: So, no, your Honor. I think that they've crafted their RFPs -- and you can look at that, Exhibit C, I believe it is -- and see that they ask for exemplars of the documents that would be sort of the shipping documents or these documents that would actually show the types of information -- the types of all information that you get upstream, the types of all information you send downstream.

When we talk about RFP Number 1 and Number 3, which

are two of the four that are in dispute for the Court today, we're just talking about documents sufficient to identify quantity, units, NDC, batch, lot, and expiration date.

It is RFP Number 6 that they contemplate -- they knew that would be burdensome, right, to go get all of the underlying source documents. So what they were trying to do is say give us this detail of these key tracing elements, if you have them in the ordinary course of business, that you can get via a reasonable search, which would be a database search. That's 1 and 3. And then show us what those underlying documents look like by producing an exemplar, and they say of the manufacturer-included packaging and labeling and shipment documents and similar information, and they do the same for downstream, if that makes sense.

THE COURT: So, for example, if a wholesaler makes a purchase from a manufacturer, presumably -- I'm just surmising now. I don't have any personal knowledge -- there is an invoice; there is a bill of lading; there's maybe -- I don't know -- labeling information, packaging information. Is it your understanding that that is what is encompassed within plaintiffs' requests?

MS. DAVIS: That's Request 6 which is not before the Court right now because they only want an exemplar of those specific documents. And we scrambled to try to get them this week, since that sort of blew up last week, and had been

waiting, thought that would happen when the RFPs ultimately got served. We're trying to get the universe of that correctly. We're in the process of getting from each of the wholesalers those exemplar documents that will ultimately be responsive to 6 upstream, 8 downstream.

The RFPs 1 and 3 before you now are much more narrow. They are documents sufficient to identify the details of the purchases from upstream to the extent that they reflect date, quantity, NDC number, lot, or expiration date, and documents to -- sufficient to identify that same information for the sales to the retailers, and only to the extent, you know, that those can be collected by a reasonable search.

MR. STANOCH: Your Honor, this is David Stanoch for plaintiff. May I address this?

THE COURT: Sure.

MR. STANOCH: Thank you.

I think it's important to know, Judge, that documents sufficient to show I believe obviously would be that there is new data showing that for all the transactions, and then, yes, we'd have a few exemplars to show what the physical copies of things look like, to back up the data.

If they don't have data to show what we're asking for, then the documents sufficient to show might be something else besides the incomplete data that they say they have and haven't given to us yet.

I know this is akin to the argument we had with the ZHP manufacturer defendant, your Honor, where we said give us, you know, the full data for the full period for your sales. They said they didn't have it for a majority of the time period. The only documents sufficient to show in that instance, Judge, they said were hard copy invoices, and that's what your Honor directed them to produce.

MS. DAVIS: Judge, D'Lesli Davis.

It's a little bit different for wholesalers because there is -- Congress has acted on what information, that is tracing information, particularly lot information is the best example, needs to be passed on. And so this whole debate arises out of plaintiffs' frustration that Congress has said, A, wholesalers do not need to track product down to the retailer; B, wholesalers do not track or trace down there; and C, Congress has said any action inconsistent with that wholesaler exemption on tracing downstream is preempted; and any requirement that there be additional recordkeeping -- yes?

THE COURT: Counsel, hold on. You're getting into argument now, which we'll get into. I understand the argument. I just -- this is just background. We're trying to frame the issue. And you'll have time to make your argument about what the statute says and doesn't say. But I'm just trying to frame the issues to avoid a dispute in the future because once the Court rules, I don't want to have another

argument about what was encompassed within the request.

MS. DAVIS: Fair enough, your Honor. And this is Ms. Davis. Apologies for getting ahead of ourselves.

But I think that on the face of the request, this is fairly simple and fairly standard language. The plaintiffs came in and said we need you to do a reasonable search of your computer systems to get us line items, a summary of the line items of your purchases from the manufacturers, in these four or five datapoints, and the same thing for below. And that's what we're fighting about.

And then in their other requests that we're not fighting about, they said get us an exemplar of each of the underlying documents.

So it is the output of the computer systems reasonable search, the ordinary course of business, kept to reflect the items they seek for each of those purchases or sales.

THE COURT: In reviewing the declaration, one of the types of documents that was mentioned was this T3 document. I think you know what I'm referring to.

MR. DAVIS: Yes, your Honor.

THE COURT: If the Court grants -- if the Court grants plaintiffs' request, for example, would the T3 document be produced? Is it in the --

MS. DAVIS: No.

THE COURT: -- scope? No?

MS. DAVIS: No. An exemplar of the T3s would be produced, but that would prove that from above, on the T3s, manufacturers to wholesalers contain lot information, and then wholesalers to retailers that exemplar will show do not contain lot information. But an exemplar would prove what we're saying to be true about the fact that tracing doesn't go downstream.

THE COURT: And then plaintiff can do whatever they want with the information that's provided on the T3 because their consultant/expert seems to think that even without the lot number, they can do some traceability, right?

MS. DAVIS: I don't think I agree with --

THE COURT: You may disagree with the expert, but that's what the expert says, right?

MS. DAVIS: Well, he can do whatever he wants to with the exemplar of the T3, but there is not an issue before the Court that we are being even asked to produce all T3s. So we would have -- so that would also be outside the scope. In the same way that you were talking to Mr. Goldberg, that would be outside the scope of plaintiffs' failure to demand those or ask for those and failure to brief them as macro issues.

THE COURT: I know, but isn't plaintiff proceeding in a prudent way by saying, okay, give us the data, give us examples, we'll take a look at the examples, run it by our

consultants to see if it's helpful or not, and then if it's helpful, are you going to be surprised if they come back and ask for all of it?

MS. DAVIS: Well, I am in light of the process that the Court has put in place. Right? Which is that these issues are to be teed up now. I've never been aware that we were fighting a battle over whether we would have to produce all, you know, T3s. Is that conceivable? Yes. I think in the last phone call, after they got our reply brief, I was threatened with that and more. But it's simply not how this -- my understanding was that the process was going or the issues that have been briefed for the Court.

THE COURT: Well, I said what I said. It seems to me that plaintiff is proceeding in a very prudent fashion. Before requiring -- asking the wholesalers to produce seven or eight, nine years of T3s, for example, they want a sample, and they'll determine for themselves if it's helpful or not. And if it's helpful, I'm not going to be surprised if plaintiffs come back and say give us seven or eight, nine years of data. Nor should the wholesalers be surprised.

MS. DAVIS: Your Honor --

THE COURT: But that issue is not before us now, so we don't have to deal with it.

One of the questions I had is, you had mentioned, counsel, that you're working on getting exemplars to the

plaintiffs. Today is July 6th. We've been arguing about this for months. Plaintiff has been asking for exemplars for months.

MS. DAVIS: But they haven't, your Honor. They haven't, your Honor. This was an RFP, two RFPs that have been on hold, pending our fight over the very specific issues that are before you now. It was only after receiving the reply that they began to take the position that they have been asking for exemplars for months. They had decided that putting that request for exemplars in a request for production and waiting until they served that request for production was the way they wanted to handle it. And so once they started jumping up and down about the exemplars, we scrambled to try to do what we could with 4th of July here, and haven't been able to get a full representation, but we were not aware that they thought they needed exemplars earlier. That was a on hold, agreed to RFP.

THE COURT: Okay. One of the cases that was cited, I think in the plaintiffs' papers, is *Androgel*, if I'm pronouncing it right, antitrust litigation from the Northern District of Georgia in 2012. In that case, the Court ordered the same wholesaler defendants that are at issue in this case to produce all "purchase and sales data," "purchase and sales data" regarding particular drugs. Is that the same or different than what plaintiffs are asking here? The

production in that case, "purchase and sales data," is that different than what plaintiffs are asking for here?

MS. DAVIS: I'm not sure that I have enough detail from that case to know the specifics of systems and particular parameters, but the three cases that the plaintiffs cite for authority that we must turn over sales and pricing information are two antitrust cases and one competitive pricing case. So I understand the temptation to think of these things and these sales and pricing data as something that just must be turned over in big cases, but wholesalers reside in a different place, and the relevance, which has never been articulated in this particular case, where the real -- the image information is, A, within the custody of the plaintiffs, and the very same information that plaintiffs seek from this computer system is being produced by the manufacturers and the retailers. We have got a real burden duplication issue as well.

THE COURT: All right. Let me -- I don't want to conflate the two issues that we have to deal with with regard to the wholesalers.

The what I call the plaintiffs' requests for tracing discovery, is that different than purchase and sales data?

MS. DAVIS: I don't think so. The way we think of it, and what I think you would call tracing information, and the items that we believe the manufacturers are producing and the retailers are producing, is this computer output of the

date and the detail of a purchase from a manufacturer, and there is a component of that that has the gross price paid by wholesalers, and downstream, the gross purchase price paid by the retailers. That would all be within the tracing, even though there is pricing information in there.

The second category then is sort of the profit or net price piece, which is not contained within that computer system, and, in fact, does not exist.

THE COURT: Mr. Stanoch, turning to you for a moment, and maybe we could just get right to the point. On this first issue regarding the requests for tracing discovery, if the Court grants plaintiffs' request, is what you're asking for the Court to order that document requests 1 and 3 have to be responded to?

MR. STANOCH: Your Honor, David Stanoch.

Yes, 1 and 3 would need to be responded to, correct.

THE COURT: And are requests 2 and 4 the second issue that we're going to deal with after we get through with the tracing issue?

MR. STANOCH: Correct, your Honor. 2 and 4 are simply the pricing aspect that would accompany the tracing data, but we broke it up separately and that's the way it is briefed.

THE COURT: Okay. So let's now get to the meat of it. Let's argue the discoverability of the information

requested in requests 1 and 3. We'll deal with the tracing issue first, and then we'll get to 2 and 4 after we're done with this. So this is -- well, let me start this way.

Defendant, can it be reasonably disputed that for discovery purposes, it's a relevant issue for plaintiff to try and find out the source that each of the plaintiffs -- where they got their valsartan from, to trace it up the supply train, just as a general matter? Can it reasonably be disputed that tracing information is relevant for discovery purposes?

MS. DAVIS: Yes, your Honor, it can, because it does not, A, tend to prove or disprove an element of plaintiffs' claims, what sale or purchase was touched by the wholesalers.

THE COURT: I don't understand how you could make that argument. I'm just totally flabbergasted that you could make that argument. Here's why.

MS. DAVIS: Here is the truth -- I'm sorry, your Honor.

THE COURT: Hold on, hold on.

Here's why. If the manufacturers are going to admit that every single piece or pill or tablet or dosage of valsartan contained whatever contaminate they found in the test, this would be very, very easy because then plaintiffs wouldn't have to prove they took a contaminated pill. I don't think that's the position the defendants are taking.

They're taking the position, as I understand it, that not every bit of valsartan was contaminated. They're going to start with only the recalled valsartan was contaminated. What does that mean? That means that defendants are going to argue that there was contaminated and uncontaminated valsartan on the market. Right?

MS. DAVIS: Yes, your Honor.

THE COURT: In order for a plaintiff to recover, don't they have to show that they took the contaminated valsartan? And how can they prove that, unless they can trace it?

MS. DAVIS: So, your Honor, that is the stated, argued relevance of the information. The problem is is proven by the evidence before you, the proven personal knowledge evidence, not the speculation evidence from the plaintiff's expert, but the proven, personal-knowledge-based evidence from people within the companies is that there is no information that the wholesalers maintain that will demonstrate which lots went where downstream. So what we have is whole- -- sorry -- manufacturers producing documentation that will show what lots they sold to wholesalers.

THE COURT: Right.

MS. DAVIS: So you go to the next step. Does anything that the wholesalers have assist anyone in determining what lot went where? And the proof in the record

before you, Judge, is that the answer is no, and it's no because Congress said that wholesalers don't have to slow down the supply chain to take the time to enter that information downstream.

So we come back to the relevance. If the documents, eight years of computer searches that will take the time and the money that the declarations reflect to create, will not assist the plaintiffs with the one reason they say they want them, product tracing. There is no relevance, and there is not a record before you of relevance or proportionality or, to the extent that we're in your *Major Tours* analysis, reasonable accessibility and good cause.

And in response to the proof that the wholesalers have put in front of the Court, what you get is simply from the plaintiffs there can be little question this data is highly relevant. It's at the core of what needs to be produced, it's fundamental, it's a basic obligation. But when the rubber hits the road, they just speculate, and they say one of two things. They say either the wholesalers are lying, there is lot information there, or, heck, if you haven't kept lot information -- and they say this in their papers but they've literally said it in the meet and confers -- then you're going to be punished. You have to produce all this stuff anyway. Because even though we can't articulate and our plaintiffs' expert fails to articulate one use we would make

of date information or quantity information or NDC information, we should be able to look at that and we'll figure it out later. And that's the definition of a fishing expedition. Never mind that there is no wholesaler wrongdoing alleged. If this is simply to get to product identification, apart from an assertion that wholesalers were at fault, it doesn't get them there. It's not relevant. And if you find that it's marginally relevant, it can't possibly be proportional when the plaintiffs can't tell you exactly how they're going to use it or what it will prove.

THE COURT: Is it the wholesalers position that in the absence of a lot number, it's impossible for the plaintiffs to trace up the supply chain from the retailer to the wholesaler, to the finished dose manufacturer, to the manufacturer?

MS. DAVIS: Yes. And I think our declarations say that literally. We can't think of a way to do it, so the burden is back to plaintiffs to tell us how they would do it, and they haven't and they can't.

To get factual for just a minute, what happens is a manufacturer manufactures a drug and they stick it -- I'm generalizing here, but they stick it into two types of bottles. One is a bulk bottle. It's got 500 pills in it, it's got a thousand pills in it. Another type of bottle is the small. Maybe it's got 30 or 90 pills in it. So on those

pill bottles, they stamp the lot number -- and this will all change in 2023 when all these systems will be speaking to each other, but they can't right now. They put a sticker on there that has the lot and the expiration date on it, and put it on that T3 and it comes down to the wholesaler. The wholesaler gets these on a pallet, a pallet of 25 500 bottles or 45 30 pill bottles. They break up that pallet immediately, and they put those pills at the distribution center on the shelves in a way that you would take the, you know, the oldest out first. They do not stop and enter manually into any of their systems -- and Congress says this is exactly the way it should be because they don't want to slow down the supply chain. They don't take time and manually enter that into a system.

So then when the retailer orders some of these bottles, take the 500 bottle, the wholesaler ships that down to the retailer without lot information, without -- other than what is on the bottle, right? But that never gets input into any sort of system so it's no longer traceable. And then that goes to a distribution center for the retailer, who sends it somewhere, or if it went straight to that retailer, if it's a bulk bottle, they take those 500 pills and start putting them into those yellow 30-pill bottles.

So there are really two levels that we lose the traceability. We lose it when we get it from the manufacturers, and then as things are disbursed further down

the chain, they get lost there. So the best place to find it is in the plaintiff's hands, with the bottle that he got.

THE COURT: Plaintiffs, I have and you have seen a declaration from plaintiffs' consultant that disagrees with the declarations that the three wholesalers have submitted. Plaintiffs' consultant says there are many ways to link a dispensed product to a lot besides the lot number. Plaintiffs' expert says that the wholesalers have more than enough information in their inventory systems to be used to do the tracing and that the wholesalers are well poised to identify how best to do this linking. I can go on and on and on.

I've read the affidavits, the declarations from the affiants of the three wholesalers. They say the exact opposite. They say it's impossible, that no such data exists, and that -- exactly what you said, that without the lot numbers, they can't do the tracing.

Now, you're asking the Court to accept as fact what your affiants have stated in their affidavits. What is the Court to do if we have this contrary declaration? If this were a summary judgment, the summary judgment would be denied. So what is the Court to do, if the plaintiffs have made their case -- of course, the defendants disagree with them. Why am I bound to accept as gospel what the defendants' affiants say when it's disputed by plaintiffs' consultant?

MS. DAVIS: Because it's based on personal knowledge of the recordkeeping of the wholesaler defendants, number one.

Number two, because the plaintiffs' expert is speculating on its face -- on the face of the declaration.

And, number three, because the plaintiffs' expert never does what I think the Court anticipated was his obligation, and that is to say, well, if there is not lot information, I would use X, and I would use it in this manner to try to recreate some form of traceability.

So we say, on personal knowledge, we don't have lot information. He says, surely you have lot information downstream, based on speculation. He does not go another step further and say, here's another way to get there.

And so when you have an expert, a consulting expert that may have time in the industry but not time at wholesalers, I don't think, and he is guessing what must be there, and you have people with personal knowledge of the systems and the data saying it's not there, and there is no step further, no creation of a particular use of a particular datapoint, I would submit, on summary judgment, that expert wouldn't carry them --

MR. STANOCH: Judge, I thought that question was addressed to me, your Honor. I'd like to --

THE COURT: No, no, no, no. Mr. Stanoch, I'll get to you.

MR. STANOCH: Thank you, Judge.

THE COURT: Defendant, let me ask you another question. Okay?

MS. DAVIS: Yes.

THE COURT: We know what happened with the discovery of the contamination. We know there was some recalls. So the FDA recalled a specific lot. I don't have a number in front of me. It could be any number. Make up a number. The FDA goes to McKesson, the FDA goes to AmerisourceBergen, the FDA goes to Cardinal Health and says we know this lot number was recalled. Can you tell us if this lot number was in your hands? Are you saying that the wholesalers couldn't find out that information?

MS. DAVIS: No, but I'm saying it's not done the way that people might guess that it's done.

The wholesalers, McKesson specifically -- I can speak very particularly for McKesson -- does not track recalls by lot number. They use the NDC number. So Teva's 90-pill bottle of Valsartan Version 1 at this dosage has an NDC number that's uniform and used by everybody. So what happens when there is a recall is McKesson sends out an alert to its distribution centers and says, hey, this lot of this NDC number is on recall, and then an employee goes and individually hand inspects the area of the distribution center where that NDC number sits, looking at the pill bottle stamp

the manufacturer put on it, to pull the suspect -- it's not suspect, that's the wrong language -- but to pull the recalled product out and put it in quarantine for reclamation.

THE COURT: How about this question, hypothetical, of course. A prescription is filled at a pharmacy. It doesn't matter which one. The consumer -- and on the label, it has the NDC number and it has the lot number, on the label. The retailer provides the lot number. They open the bottle, there is a foreign object in the bottle. The FDA comes in and says, we got to take all of these lot numbers off of the market. The FDA goes to the three wholesalers and says, here's the lot number, take all of this off of your shelves. Are you saying that the wholesalers couldn't do that?

MS. DAVIS: No, I'm saying they can do that, but they would be guided by the NDC number. So the contaminate is in Teva NDC number -- Number 1, Lot Number A. So that's going to make that information from the FDA or from whomever, however it comes to be recalled, if it's a manufacturer recall, it's going to be sent out to the McKesson distribution centers by NDC Number 1, Teva Number 1, go look on your shelves for Teva Number 1, and then, when you're in the area of Teva Number 1, check to see if we have any of this lot, and if we do, do whatever you're instructed to do.

MR. JOHNSTON: And, your Honor, Sarah Johnston, just briefly, to correct something that was said just a moment ago.

The pill bottle that the consumer would have in his or her hands would not have a lot number on it. It would have the NDC. So the tracing that we're discussing is related to the NDC. But, by and large, that pill bottle from a pharmacy is not going to have a lot number, you know --

THE COURT: Well, Ms. Johnston, I have to respectfully disagree with you because I just walked over to my dresser to look at the bottles of the prescriptions I take for my high blood pressure. And the first one I picked up has a lot number on it.

MS. JOHNSTON: Well, your Honor, I understand that --

THE COURT: And another one has a -- another one has a batch number on it.

(Crosstalk.)

MS. JOHNSTON: Which is why I qualified the response to say that there are certain smaller pharmacy chains that do -- that do print lot numbers or do maintain lot numbers, but the -- and, again, this is not something -- an issue that's --

THE COURT: From CVS.

MS. JOHNSTON: That's a surprise to me, your Honor, and an experience that is not reflected in what -- what I've recognized socially or experienced with my own client. But I appreciate that.

I wanted to jump in though, because it is and

continues to be an issue for the pharmacies that that -- while I can't speak to your own personal experience, your Honor, that's not something that is traced at the consumer level, and that is what we have communicated to plaintiffs on numerous occasions.

THE COURT: Luckily for me -- luckily for you, I'm sorry, you're not as old as me so you don't have to take these prescription medicines yet. Someday you might be that old.

But, anyway, Mr. Stanoch, I'm sure you're chomping at the bit to say something. Do you want to be heard?

MR. STANOCH: Yes, your Honor. Only briefly. This is David Stanoch, for the record.

Your Honor, one of your questions really hit the nail on the head, that the information -- the traceability information is obviously relevant. And I've heard Ms. Davis reference proof, that she was getting factual, talking about evidence.

Judge, we're talking about the facts that I am allowed to get to develop the record to get factual to argue these things. I don't have to accept Ms. Davis's representations on this call about what does and does not exist. That's not how the litigation works.

I'm entitled to the information, in whatever form it is, and then I can ask questions of her declarants about the information to see what other information might be out there.

That -- there are a number of examples I can go into, of many, your Honor. I mean, Ms. Davis's declarant, Mr. Mooney, says they don't have it, she says they don't have it. We have public information where he makes a statement that product identifiers are important to recall is the quote -- recall a portion of a batch made during some time frame of one day at one plant, end quote.

The facts are necessary for us to get in the first instance before we can even have these next questions.

And to say that our expert is speculating, our expert cites publicly available information from these very defendants and what they keep, and I can't have my -- it's prejudicial to have my expert faulted for, quote, speculating, when they won't give me a single fact or document or data that we can actually look at. Ms. Davis says, well, the expert -- it was incumbent on the expert to come up with the alternative method now. I don't even have the information from them that I could give to my expert for him to go ahead and to look at. We're three steps ahead of where Ms. Davis and these defendants think we are, Judge.

THE COURT: What do you say about counsel's statement, as I understood it, that you didn't ask for exemplars until, what, a day or two ago?

MR. STANOCH: Your Honor, I'm not going to rehash that from the other week. We think it's clear we wanted

exemplars for awhile. Of course, it's one of the specific document requests in the set that we prepared. That's the formality of doing it. We wanted exemplars or samples from any of these defendants. Not a single one of these defendants, your Honor -- we served the draft request December 2019, seven months ago. None of them have released any documents to date. No exemplars, no documents, no data. We have two lines of data that McKesson finally gave us that we saw for the first time when they served their letter briefs the other month. That's it.

So the idea that we didn't want these exemplars or data or samples or terminology, I will just say that I disagree with that. And, regardless, your Honor, they can come to us to let us know the name of what all the fields and data and forms are. They never -- she's talking about T3 reports. Judge, we never heard about that until the other week. We don't need to guess what forms or data or records that they may have.

MS. JOHNSTON: Judge --

MR. SLATER: Your Honor, it's Adam Slater.

I just want to add one thing to what Mr. Stanoch said before, and then defense counsel can respond, because I happen to have in front of me an excerpt from the February 26, 2020, transcript, on Page 15. I don't have the pages enlarged because the excerpt was e-mailed to me a moment ago. But

there was a specific discussion about getting the exemplars from the wholesalers and retailers. And I'm quoting from your Honor saying: "I think that's a great idea to help advance the ball to get exemplar documents, and I would encourage the wholesalers and retailers to do that. Experience shows that if we can get these issues resolved once and for all early, it saves so much time," et cetera. So I just wanted to make it clear that this wasn't something that was raised a week or two ago. I don't know how counsel can say that. And I'm reading from again the February 26, 2020, transcript at Page 15. I'm trying to leave this to Mr. Stanoch, but I thought it was important to add that to the record.

THE COURT: Am I correct, though, that there were exemplars produced by the retailers?

MR. SLATER: I will leave it to Mr. Stanoch to answer that.

THE COURT: Or at least they have agreed to produce exemplars.

MR. SLATER: There has been a lot of discussion about what may or may not be produced, but in the long -- in the months and months and months of going back and forth, we don't have what we need, I think is the bottom line. There may have been something produced. I will leave that to Mr. Stanoch to respond. I don't recall seeing anything, but it's possible. But at this stage, to be in July, and not have a full set of

exemplars, is, you know, from our perspective, it's, you know, obviously frustrating.

MS. DAVIS: Judge, putting aside the -- this is D'Lesli Davis.

Putting aside the exemplars for a moment, though, the Court ordered that the plaintiffs had the burden to get an expert -- who was going to have a hidden name and we weren't going to be able to attack credentials or who he was, that was going to be in camera -- but he had to carry the burden of relevance and proportionality. And now that they tried to do that, and we responded with -- and it had to be an admissible proof, and the judge instructed us you have to prove up your burden too, and you have to counter this in admissible evidence. And now that we've done that, they say, oh, this is crazy. How can they expect us to put any of this proof forth when we haven't even gotten to do discovery yet? So this was the process, this was the burden, this is the D-Day, and they haven't created a sufficient record of relevance, not to -- and we haven't even talked about the burden stuff -- but of literal relevance. And if they needed more time or whatnot to try to determine that, they could have requested it. But they wanted to go forward on July 6. So arguing that they need to -- you know, because you don't have this lot information, because Congress says you don't have to have it, and that claims based on that and recordkeeping claims based on that

are preempted, but now, hey, why do you expect us to know anything till we start getting all this discovery, it puts the Court's whole process on its head. Of course, you wanted them to come forward with proof of relevance. Of course, we had to counter that, and we did.

MR. STANOCH: Your Honor, may I respond?

THE COURT: Sure, go ahead, counsel.

MR. STANOCH: Thank you, Judge. This is David Stanoch for plaintiffs.

Judge, I disagree with Ms. Davis's characterization of why we need a declaration in the first place. The point, I believe, was your Honor wanted a declaration from our expert for him to say that we needed the data and what types of data probably exist. We did that. We were not required to disclose his full methodology and put forth a full model showing, from soup to nuts, *Daubert* proof, about how he's going to do traceability. I don't think the Judge contemplated that. I don't think it's specifically possible, given the posture we were in. And I'll just leave it at that.

THE COURT: What I'd like to do now is, Defendant, we've talked for awhile, we're still on this tracing issue. I want to give you an opportunity to argue whatever issues, whatever point you want to make regarding why the Court should deny the request to respond to requests for production 1 and 3, and then I'm going to give plaintiff a chance to respond,

and then we're going to move on to the next issue.

So, you've answered my questions, Defendant, and I want to make sure you have a full and fair opportunity to make whatever argument you want to make, to the extent it hasn't been done, regarding what we've been calling this traceability discovery should not be ordered. So the floor is yours.

MS. DAVIS: Thank you, your Honor.

I think what the back and forth has proven is that the question here and now is whether there is a sufficient record of relevance, proportionality, reasonable accessibility, and good cause squarely within your Honor's *Major Tours* analysis, to support the plaintiffs' just desire, based on what we believe to be speculation from their expert, to impose these two heavy discovery requests on the wholesaler defendants. And these are defendants that, despite three tries from the plaintiff on the economic loss case, have failed to assert even one claim of factual wrongdoing. What they assert is that the wholesalers failed to test the drugs. What they don't allege is any fact to show that the wholesalers knew there was a problem or put on any sort of even constructive notice of a problem prior to the recall, any statement wholesalers made about the drugs, any improper dealings whatsoever about the drugs, and, frankly, you have to get to Paragraph 411 of the economic -- of the third version of the economic loss complaint to get to that allegation, or

to figure out that there's nothing there. And why is that? It's because of who the wholesalers are and what they do. They're just middlemen in the drug supply chain. They pass through sealed containers from manufacturers to retailers. So what don't they do, right? They don't manufacture it. We didn't manufacture any of the drugs taken by the plaintiffs, and we didn't actually sell it to the plaintiffs.

So, second, we don't keep eight years' worth of financial and sales data sitting around with regard to VCDs only.

Third, the wholesalers do not track downstream lot and expiration information that they receive from the manufacturers.

And the only argument against the proof from all three wholesalers that that information is not tracked downstream is plaintiffs' expert and the plaintiffs' briefing saying we just don't believe you.

Fourth, we've proven that the wholesalers do not know of any way to trace, other than the lot information, which lots and which product went to whom downstream. And, in response to that, there is no articulation of any method by which the plaintiffs' expert could use any of the information that is available and that your Honor's contemplating ordering to get there. So it would be futile.

What we also know is that Congress has acted in this

space, and has said that wholesalers, specifically, are not required to include that lot number on the downstream sales and are not required to trace that information. It's called the wholesaler exemption to the Drug Safety and Security Act, and it's a thing, it's a real thing, and Congress has backed it up with a preemption provision that says that the states may not in any way impose any burden on wholesalers beyond the tracing requirements and the tracing exemptions within the DSCSA. And that goes for the recordkeeping rules as well. Nothing inconsistent with or more stringent than that. That's going to be preempted.

But what the plaintiffs have said is, well, we're going to make you produce all this stuff because you chose not to keep lot information. And that is exactly the type of punitive measure through a lawsuit that the Act is trying to not have happen to wholesalers. But that's what the plaintiffs are asking you to do, to use your authority under the law of the various 50 states to harass wholesalers on this product tracing thing, when they are squarely within the area that Congress anticipated and made, you know, provision for. So, you know, they just speculate, they throw at the wall a few ideas, they reference some things, that they don't even attach in their reply brief. And if it is true that lot and expiration information is not traced downstream, and if it is true that the record before you demonstrates no way that the

other information that is available would either tend to prove or disprove product tracing, or could be used in some machination by their expert to get to product tracing, then it's simply not relevant.

So, if it's not relevant, what about the burden? Well, we've proven up the hours that would be involved I think is about 140 hours -- I'm sorry -- 140 NDC numbers that would each take three hours per NDC number just to query for one report. And we did that calculation just on the recalled NDC numbers and came up at 130,000. Your Honor, this duplication of effort issue is not minor when you begin talking about burden and the proportionality and the good cause analyses that your Honor is so familiar with.

The manufacturers have said, have agreed, they will produce this very information that we're talking about. The manufacturers are going to prove the date of sales, to which wholesaler, the quantity, the NDC number -- right? -- and the gross sales price. That is exactly what the plaintiffs are seeking from wholesalers, just on the other end of those transactions.

The retailers have agreed to produce the detail of each of their purchases, which will say the date of the purchase, the wholesaler purchased from, the quantity purchased, and the gross purchase price. That is exactly the other RFP, RFP-III that they're seeking. Exact duplication.

So no relevance, exact duplication, excessive cost to wholesalers to begin pulling all these. So where are we on proportionality? The importance of the issues at stake in the litigation? Yes, of course it's important, although that leads to the second, the amount in controversy.

We've got a small amount of an inventory of plaintiffs who've been personally injured, and we have overwhelming evidence that with regard to the economic loss case, these plaintiffs would have had to buy a replacement drug, and they are not out dollars to the extent that they claim to be. So I would argue the amount in controversy is not what the plaintiffs have represented it to be.

Parties' relative access to information, the manufacturers and retailers not only have everything that the plaintiffs are seeking, they've said they will produce it.

Parties' resources, I think it's clear that all of the parties here have good resources, but I would note, in the words of your Honor, no party has an unlimited litigation budget to pay for document production efforts that, in all likelihood, are of marginal benefit. And, regardless of the relevance argument, if this is going to reproduce what's being produced by the manufacturers and the retailers, at a minimum, why not wait to see if they get everything they need on that front?

Importance of discovery in resolving the issues, I

think none. If these documents do not assist in product tracing, they do not assist in resolving the issues.

And whether the burden or expense of the proposed discovery outweighs the likely benefit, I think we've demonstrated the burden over the benefit, based on the prior argument.

I would submit, your Honor, that we've also proven that based on the work required to query the system to get this information, the information is not reasonably accessible. And, as your Court knows, if we have proven that, it's not sufficient for the plaintiffs to merely claim that our estimates are exaggerated or inaccurate. They needed to come forward and present contrary estimates or affidavits on that cost estimate, and they didn't do that.

If the Court is inclined to entertain that even further, then we're at good cause. And although the elements are close to the proportionality, they're not exactly the same. So the specificity of request, they're pretty specific, although I would note that there seems to be some lack of clarity, based on the reply brief, as to exactly what NDC numbers the plaintiffs want us to search. We thought they wanted us to search all NDC numbers of any VCD from any of these defendant manufacturers. They now make it sound like it may be something less than that.

The quantity of information available from other more

easily accessed sources, that's exactly manufacturer and retailer agreements. Everything is already on the table.

The failure to produce relevant information likely to have previously existed, I don't think that's an issue here.

The likelihood of finding new information if this were ordered produced, I think it's zero with the manufacturers and retailers agreeing to produce it.

Predictions as to import and usefulness, we've already discussed that.

Importance of issues at stake, we've addressed that.

And the parties' resources, we've addressed.

So, you know, in sum, I know that the temptation is to just view this purchase and sales information on data production, it's just something that's de rigueur for a big company in a big case, but it shouldn't be for whistleblowers. Wouldn't matter if there were 40 middlemen. If it doesn't assist in product tracing, even the plaintiffs don't claim that it's relevant.

And we're riding the line here with the DSCSA of making some really bad law. Can you imagine if wholesalers were required to produce this type of data every time there is a product liability suit, every time there is one of these economic loss cases, every time there is a big MDL?

So we think on the record before you, Judge, they're just not there on any of relevance, proportionality,

reasonable accessibility, or good cause. Thank you.

THE COURT: I just have one question, counsel, before we turn it over to Mr. Stanoch. I'm, of course, aware that the wholesalers have argued that the production of the requested information would be burdensome or unduly burdensome. Correct me if I'm wrong, but it's the first time I heard, during this oral argument, that's the first time I heard the wholesalers argue that the requested information was not reasonably accessible. Could you clarify that for me? Can you point to where in the letter briefs that the Court received there was an argument that the requested discovery was not reasonably accessible?

MS. DAVIS: So, your Honor, we did cite the *Major Tours* opinion in the brief, but we didn't use the words "reasonable accessibility," and part of that was because we were waiting to see the reply, and if there was further information or further discovery or what was going to happen with regard to our cost estimates. But what did happen was they fell squarely within what the plaintiffs had done in *Major Tours*, and they didn't attack that, other than to say we think this is exaggerated, and at that point issues were sort of joined, proof was frozen, and it became clear that we were in, with the burden we had proved, a not reasonably accessible scenario.

THE COURT: Okay. So, are you saying then it was

implicit in the briefs, or is my understanding correct, it was not specifically mentioned?

MS. DAVIS: It was not specifically mentioned, your Honor. The proof -- the proof required to demonstrate lack of reasonable accessibility on our part was put into play in our brief and with our evidence, but the words were not used.

THE COURT: Is there -- tell me if I'm wrong, but I understand the concepts of unduly burdensomeness and reasonably accessible to be a little bit different. Do you disagree with me?

MS. DAVIS: No, I think they probably are, but when you have the same facts that support the argument that, hey, it's going to be really expensive to go get this information out of our systems, with the evidence that also demonstrates that it's going to take this many hours for somebody to query, and these levels of queries that have to be done, and you've seen in the declarations where, you know, you've got to do repeat searchs just to make sure the rows that come out aren't over 400,000, and the computer freezes up, and you've got to start again. That sort of machinations then, I think on their face, underwrote the legal conclusion that not only is it burdensome but it's also, through one view, not reasonably accessible.

THE COURT: Fair enough. Okay. Thank you, Defendant.

Well, Mr. Stanoch, you have the last word.

MR. STANOCH: Thank you, Judge. And I will try to be concise because I believe our letters fully address everything Ms. Davis has raised. I'll just try to hit a few points and answer any questions, Judge.

Number one, in Ms. Davis's long litany, I notice she didn't mention anything about confidentiality, so I can only assume that they now agree that the discovery confidentiality order in this case is more than adequate to assuage --

MS. DAVIS: Of course not.

MR. STANOCH: -- the confidentiality concerns.

Well, and our position, Judge, is that obviously, the DCO is adequate in this case, as it is in many, many, many other cases.

In terms of DSCSA preemption, Judge, as we say in our papers, that's neither here nor there. We're not trying to impose an obligation on these wholesaler defendants to keep additional information. We know what the statute says and the regulations say. We've read it. But whatever they are required to keep is not the same thing as what they do keep.

And, your Honor, we've shown, both with the underlying facts we were able to find publicly available with our expert in his declaration, plus additional facts that we found publicly available from defendants' own websites, showing that their customers can query these types of reports

and show lot numbers, in their words, subseconds. So we've put the available facts that we have in there as necessary.

In fact, we cite the Form 483 that was issued by the FDA to McKesson because Losartan, one of the products in this case, McKesson sold Losartan to Albertsons, both defendants here, because Albertsons was complaining it didn't have lot and expiration date on it.

So I think there is a lot of other evidence in the letters that we cite, Judge, but we think that to the extent you even need the evidence at this pre-discovery stage, there is certainly enough in there to show that we are at least entitled to understand what information does exist in these defendants' records, whether or not that is more, the same, or less than what the DSCSA requires. We think we've shown the likelihood of new information is very high, and that given that these defendants' own customers can request this information, require this information in these wholesalers' own systems, there must be some -- there is information there available, and it should be produced.

MS. DAVIS: Judge, may I just address the McKesson connect and the 483?

THE COURT: Last word, counsel.

MS. DAVIS: The McKesson connect is an outward facing app for pharmacies, and it allows a pharmacy to go in and search the last two years, so that would nicely line up with

the recalls. We wanted to talk about two years, instead of eight. But allows them to search their purchases for McKesson for the last two years, but lot and expiration information is not in there unless the pharmacy itself puts it in there because, obviously, we don't track that way.

The 483 warning letter relates to the specialized area of suspect product which, in lay terms, means if product comes through the wholesalers that, without opening the sealed container, they should be able to eyeball and see that there is a problem with, they need to capture that suspect product and set it aside. So that doesn't relate to being punished for not tracking lot or expiration information. It said, you got a set of product that, from outside, you should have been able to see there was no lot information on and you didn't set it aside, something completely different. Thank you.

THE COURT: Thank you, counsel.

Okay. We're going to move on to the second issue, which involves requests for production 2 and 4 directed to the wholesalers, and this might overlap a bit with the retailers' dispute, as well, so I can understand if the retailers want to weigh in.

I have a couple of questions for the plaintiff. I don't know who's going to address the issue for the plaintiff. Is it you, Mr. Stanoch?

MR. STANOCH: I believe so, your Honor.

THE COURT: Okay. With regard to whether this -- I'll call it the pricing data -- is relevant, is it plaintiffs' position that the requested discovery is relevant to their unjust enrichment claim and their disgorgement claim?

MR. STANOCH: That's partially correct, yes. We think there is more to it, but yes.

THE COURT: Okay. Tell me. What else is it relevant to?

MR. STANOCH: Your Honor, as we put in our reply brief, we think restitution, disgorgement, are broad, equitable remedies, always available in this Court's arsenal, as well as under the law of many of the states that are alleged in the master complaint. So we think it should not be cabined as sort of the unjust enrichment only method of damages. But, aside from damages in general, as we put in our opening letter, you know, the price is paid by the wholesalers, and, in turn, what they charge downstream are relevant to motive, intent, and notice. And there is -- it's in the public filings and pleadings in this case of other defendants in this case saying the pricing of some overseas drug was suspicious, in fact, and if there is such a drastic price differentiation between foreign overseas valsartan and domestically made valsartan, that is a reason that, we could certainly argue to the finder of fact, should have made it known or reasonably should have known through investigation to

the downstream defendants that there was something amiss here, and there must be a reason why. And --

THE COURT: So you mean in every case where a consumer alleges that a product cost too much, they can get this profit discovery because they want to show motive, intent, and notice?

MR. STANOCH: Well, no, your Honor. I think here we have --

THE COURT: Is that -- that's what you're arguing, isn't it?

MR. STANOCH: I am arguing that it is a basis for the discovery, yes, but I am not arguing it is a basis in every single case where someone said the product was too expensive.

What we're saying here is that there is already in the public record, in the pleadings and the complaints and otherwise, statements by other defendants actually calling out the pricing here and statements by other defendants saying that they cut low prices on purpose, and there is enough evidence to suggest that there is a reasonable basis --

THE COURT: Oh, I see.

MR. STANOCH: -- the situation that happened here.

THE COURT: I see. You're saying because the purchasers got such a good deal and the prices were so cheap, that they should have questioned whether there was a reason why the prices were so cheap. Is that what you're saying?

MR. STANOCH: Correct, your Honor.

THE COURT: Okay. So if Walmart sells Tide detergent $3 less than Shoprite, purchasers should be put on notice that the Tide Walmart, by itself, is somehow defective compared to the Tide that Shoprite sells? Is that what you're saying?

MR. STANOCH: No, your Honor. No, I'd say if I'm a distributor, and I'm buying valsartan from one person, I'm making it up for $10 a bottle, and then -- someone who sells in the U.S., and then someone from China comes to me and says we'll sell it to you for 50 cents a bottle, I think the magnitude of the delta is such that someone exercising reasonable diligence would have to question that and do due diligence to see what, if anything, might be the explanation.

THE COURT: But isn't that why people -- listen, I'm not an expert on manufacturing, but isn't that why so many products are made in China, because maybe they don't pay a minimum wage or have the environmental regulations? So if someone buys a cheaper T-shirt that's made in China, they should question whether it's defective or not? That's not your strongest argument, counsel.

So we know you're arguing this pricing information is relevant to damages, motive, intent, notice. Anything else?

MR. STANOCH: No, your Honor. Those are the principal reasons.

THE COURT: Can you tell me -- and I have to

understand this because I think it's important -- how this pricing requested discovery, if it is, is relevant to class certification?

MR. STANOCH: At the class certification stage, your Honor, I'm sure you know, the plaintiffs will have to come forth with a damages model showing that damages are susceptible to classwide proof. And that's usually done, traditionally, with an expert modeling damages for a defendant or group of defendants. For that model to be put together, we need all of the inputs -- what was bought, for how much, who you sold it to, for how much. The delta between those two things are your ill-gotten gains, which we would say are class damages. Again, please don't hold me to it, because it's premature at this stage, but speaking very generally, that is the usual procedure.

THE COURT: Do you have to produce an actual report computing the numbers -- you being the plaintiff -- or does the plaintiff have to say if I get this data, this is how I would put together the damage model?

MR. STANOCH: I think the defendants in the case will argue that Third Circuit law requires plaintiffs to put together the model and use the data to show how -- to run the model, using the data.

THE COURT: So if, hypothetically -- I'm not ruling right now -- suppose the Court says no, we're got going to

give plaintiff this pricing data because the defendants have argued it's irrelevant, burdensome, et cetera, et cetera. Do you think that the Court would then permit the defendant, who has argued this information is not discoverable, that it's a basis to deny certification? In other words -- I didn't say that as clearly as I should have.

Do you think it's reasonable or feasible or possible that plaintiffs can rely on the fact that the -- I'm sorry -- defendants can rely on the fact that plaintiffs have not produced a profit model, when the defendants refuse to produce the profit discovery to the plaintiffs?

MR. STANOCH: Unfortunately, your Honor, I believe it would be an argument used by the defendants against us, and they would probably say that it was plaintiffs' burden to show every element as susceptible to classwide proof, including damages, and that we did not get the information that we sought, and that we do not find an adequate alternative to that, shows that we cannot prove on the a classwide basis the element of damages. And that's why we say if they would agree to waive or stipulate that they won't oppose class cert or raise a defense at another point, then we can certainly think about that and maybe we can have a compromise. But, absent that -- and we have floated this before, and not a single defendant has agreed, and I'm not surprised. But, absent that, if we have no guarantee that the fact that we did not

get the information, even if your Honor says -- precluded us from getting it, it's still our burden, and we have not discharged our burden. And that's a situation that we can't have ourselves in, unfortunately.

THE COURT: Question for you.

MR. STANOCH: Yes, Judge.

THE COURT: We read the cases that the plaintiff cited where the Court has ordered the production of pricing and profit information. We're not dealing with the punitive damage issue right now. We're not dealing with an antitrust case. We're not dealing with a patent case.

Have you cited one case -- and, obviously, I'm not deciding the merits of the claim. This is not a Rule 12 context. So, just to be clear, I'm not ruling on the merits. Of course not. But have you cited one case in the product liability context where a Court has said that the plaintiffs are entitled, in discovery, to this type of profit information, pricing information? One case?

MR. STANOCH: I think, though we probably did not -- we certainly did cite it in our reply brief, cases that allowed state law claims to go forward, as well as certification of a New Jersey unjust enrichment class, and a Minnesota Consumer Fraud Statute class, which was *Hudock versus LG Electronics*, 220 Westlaw 1515233, and in that opinion, the damages model put forth for unjust enrichment

relied on that information.

So, to your direct question, no, we did not specifically cite a case on a discovery posture, but there was certainly the cases saying, on certification, that that was the proper damages and proper inputs to show any damages model.

THE COURT: Question for you. Who is it -- we have three master complaints. Which set of plaintiffs are asserting this disgorgement, unjust enrichment type claim? Is it all of them or one group or some combination?

MR. STANOCH: I believe it's some combination, Judge. It's certainly the master economic loss class action complaint. I believe, I don't have it in front of me, that the short-form complaints for personal injury cases have a check box for number of state law claims for that individual plaintiff, and I believe it may include unjust enrichment, though I do not have it in front of me, and I do not recall either way whether the medical monitoring complaint had unjust enrichment or not in it.

THE COURT: Okay. Hypothetical, again, I'm making this up. Suppose the case goes to trial, and the plaintiffs win, and the jury says there has been $100 in profit. Who gets that money?

MR. STANOCH: Would that be a economic loss case, your Honor?

THE COURT: Let's assume it's the economic loss case. Why would those economic loss plaintiffs, the third-party payors, why would they get that profit? They didn't -- it's not a damage to them, is it?

MR. STANOCH: It is -- the principles of disgorgement and restitution is so that a defendant does not benefit from it's own wrongdoing, and that the law under the various states, and I believe the federal law in terms of it being an equitable remedy valuable, is to deter that and to put it in the hands of the next best, which are the plaintiffs, who would have been harmed by the sale of the offended product.

THE COURT: Okay. Suppose I buy a toaster, the toaster is defective, I'm injured, I go to trial, I win. The jury says the toaster is defective. Am I entitled to the profits that the manufacturer made on that toaster?

MR. STANOCH: I would argue yes, Judge. The *Hudock* case with the New Jersey unjust enrichment class and the Minnesota consumer protection class, that was a case by consumers against LG Electronics, the appliance and television manufacturer. They weren't seeking Walmart or Best Buy's ill-gotten gains. That was ill-gotten gains by the manufacturer, LG Electronics.

THE COURT: Okay. In this context, are you seeking the "ill-gotten gains," the profits from the manufacturer? In the present context, where we're dealing with the wholesaler,

retailer issue.

MR. STANOCH: Yes.

THE COURT: So are plaintiffs totally missing the mark then? In every single product liability case that is filed from here on out, if a plaintiff's attorney was doing their job, they should seek disgorgement of profits, in addition to personal injuries?

MR. STANOCH: I can't speak, obviously, what other lawyers should do in every future products liability case, Judge, but we think the facts in this case will be sufficient to show that the defendants in each of the steps with the contaminated fraud is different than, say, a toaster with a handle that didn't quite work or the heating coil didn't get as hot as it said.

THE COURT: Do I take it that plaintiffs are also seeking this type of remedy from the manufacturers?

MR. STANOCH: We are, yes, Judge.

THE COURT: I know it's not an issue before the Court now, but are there ongoing discussions with the manufacturers about whether this type of what I call profit, sales type information, is going to be produced?

MR. STANOCH: Yes. In fact, the pricing or cost information was part of what the defendants did produce, and your Honor will recall from a couple weeks ago, there were talks with questions we had about one or two particular

defendants' data, and some of those questions related to how they tracked the cost side, the profits, so to speak, on the sales of valsartan, whether it was by customer or whether it was through product levels, in other words, did we make five cents a pill or did we make $500,000 for all sales to the company. So, regardless of the question of how it was kept and maintained, it was data in some form, at least, I think was produced by most, if not all, of the manufacturer defendants by now.

THE COURT: Another question for you. You're seeking the same type of data from the wholesalers, retailers that you're seeking from the manufacturers in terms of the profit type information. Am I right about that?

MR. STANOCH: Yes, Judge.

THE COURT: All right. Do the issues rise or fall together? In other words, hypothetically -- I'm not ruling right now -- suppose the Court says no, you're not going to get it or at least you're not going to get it now from the wholesalers and the retailers. Does that necessarily mean that the same position has to be taken with regard to the manufacturers or are the situations and claims different or distinguishable?

MR. STANOCH: I think it may be hard to distinguish between them, Judge, and here's why. If a given manufacturer -- I don't want to pick names because I want to

be sure, but I know there is data from a manufacturer that doesn't keep or said it doesn't keep data on its profits selling per customer; it just says, you know, we sold X amount of valsartan, 160 milligrams, we made X amount of dollars. Right? They can't tell us where the profits are coming from.

We would need the wholesaler defendants to tell us what they paid so we can then figure out what the cost of the drug was from the manufacturer down to the wholesaler, to know what the profit was on the sale of the defendants in this case, and so forth down the chain.

THE COURT: Okay. That's your argument that the discovery you want from the wholesalers and retailers, for that matter, is relevant to the damages recoverable from the manufacturer?

MR. STANOCH: Correct.

THE COURT: The profit information, pricing information from the manufacturer, is that also relevant to damages and motive, intent, and notice?

MR. STANOCH: It would be, yes, Judge.

THE COURT: Any other reasons that it might be relevant for the manufacturers that doesn't also apply to the wholesalers and retailers?

MR. STANOCH: I think it would be the same reasons for each tier of defendant, Judge.

THE COURT: Okay. All right. So I will let you have

the last word on this. I want to turn the call over to the wholesalers, and then we'll hear from the retailers, because it might be the same issue. I don't have any particular questions for you, but I want to make sure you feel that you have a full opportunity to present any argument you want as to why the requested sales and pricing information shouldn't be produced.

MS. DAVIS: So, your Honor, D'Lesli Davis for the wholesalers.

I'm confused because I thought I heard the plaintiffs' counsel first say that, yes, the manufacturers have all agreed to give us profit information, the differential between their cost of goods sold and their sale price. And then he came back later and said, oh, but we need this from the wholesalers too or we won't be able to figure out the manufacturers' profit. So I'm confused by that. I think his first position was the correct one, and there is not a need for the wholesaler information to determine manufacturer profits.

And then you had asked, your Honor, if there was a way to differentiate this unjust enrichment/disgorgement of profit claim as it exists towards the manufacturers versus the downstream defendants, and, basically, because I know we want everything from all of them, for all of their ill-gotten gains, but there is a very simple way to distinguish them.

There are many factual allegations of wrongdoing against manufacturers, starting with the failure to use good manufacturing practices, and there is only one factual allegation against the wholesalers, which is you didn't open the sealed containers and test the product.

And, as your Honor is well aware, in addition to all the things we have already discussed with the DSCSA, there are innocent sealed -- innocent sellers sealed container statutes all across the country that say if a wholesaler wants to be insulated from liability, they should not open the container or alter the drug. That's how you get insulation, and that's how you get a defense against liability.

So, the Court has been very practical in trying to approach discovery issues and, from a practical standpoint, the Court can very easily see here that when it comes to the core plaintiffs' claims, in the personal injury action their real damages are their personal injuries -- their medical expenses, their pain and suffering, lost wages, et cetera -- and they have custody and control of all of that.

When it comes to the medical monitoring class action, the damages are whatever it would be to monitor the class's health on an ongoing basis. They have access to however they're going to figure out what that is.

And when it comes to the economic loss plaintiffs, what they're saying is that each of the individual plaintiffs

shouldn't have paid for this drug, and the individual plaintiffs know what they paid for that drug, and that too is within their custody. So there is not any sort of -- well, I guess, let me back up.

The plaintiffs didn't argue anything about choice of law to you. They just randomly picked different cases that they thought were helpful. But when we went forward with New Jersey laws or the home state law of the Court, and the plaintiffs' attorney, you know, they sort of flipped out because there is some core fundamental truths about unjust enrichment and disgorgement of profits that New Jersey has recognized. And the first is that, you know, it's limited to allegations of conscious wrongdoing, of which there are zero against the wholesalers in this case. And that's not just the District of New Jersey. That's the Restatement (Third) of Unjust Enrichment. Plaintiffs haven't alleged conscious wrongdoing, and there is no place in the country, probably, that would allow a disgorgement of profits without a factual claim of wrongdoing.

And the New Jersey law, again, is an exemplar. There's two other instructive things about unjust enrichment/disgorgement of profits, and that, of course, is what they're arguing in their brief is the only thing that really entitles them to this. I think they make a side-wide throw at, you know, Court has inherent power to do that. But

the plaintiff must have conferred a direct benefit, that plaintiff on this defendant. Wholesalers are in the middle. There is no direct benefit by any of these plaintiffs, whichever complaint you want to look at, to these defendants. And unjust enrichment is available really where there is even equitable remedy, right, available where there is no other relief available. And if there is one thing that plaintiffs have done, it is that they have invoked every other possible type of relief available, both in tort, and then the UCC damages too.

So, from the practical standpoint here, the unjust enrichment claim is not even factually pled as to wholesalers, and without the facts there, when it's something this sensitive, the proprietary information, the trade secret nature has been proven up, and when the plaintiffs, after three times, don't even fit their unjust enrichment pleading -- which, by the way, is only in the economic loss complaint -- into the four corners of the home state law, there are reasons for that, of course.

And so, at a minimum, we would submit that it would be premature to jump into ordering this sort of sensitive information, with the 12(b)(6) coming up, which is simply going to argue that on the face of these pleadings, there are no facts alleged, even taking all of the allegations made by the plaintiff as true, that would support any sort of unjust

enrichment or disgorgement of profits for, you know, ill-gotten gains, and that that cause of action is going to be dismissed.

So, at a minimum, we would argue that this sort of -- these two discovery requests should be stayed.

Let me back up just a little bit, too, and point out to the Court that each of these requests seek not only gross prices, meaning wholesalers' gross prices, but the net prices. Now, "net" is not defined. And when we talk to the plaintiffs in the meet and confer, all we hear about is sort of profits, profits, profit.

And so, in addition to the demonstrated burden to pull the gross price information, which we've already discussed just with regard to recalled NDC numbers, we are also talking when we talk about true profits or true net price, even though it's undefined, we're talking about creating something uniquely for discovery, something that does not exist at the -- at the wholesaler companies currently because they do not track their profits by valsartan-containing drug or even by NDC number. So to extract the information that would be required to figure out underlying costs and give a true representation of what would be a profit figure or a net price, whether you're talking about transportation, overhead, taxes, rebates, chargebacks, whatever else, over eight years and the thousands of sales

that we're talking about, you know, we're talking about a whole new burden here that is just really staggering when you think of the different legacy systems involved, the administrators that may have been there and left, and the different functional areas, right, that would have to be involved -- IT, accountants, sales, the business units, tax, and then you probably have to go outside the company as well to get some work done on that.

So it's hard to believe that it makes sense, based on the face of the pleadings, at all. Plaintiffs should be held to their pleadings. I mean, the wholesalers deserve some protection when the plaintiffs don't allege wrongdoing, and then come and seek this highly sensitive information.

But, at a minimum, your Honor, given the burden and given the upcoming 12(b)(6)s, we would argue that not only does it make sense to table that, at a minimum, but that there is no real harm to the plaintiffs to do so. If this were to be held till, say, January, when there are rulings on 12(b)(6), the plaintiffs are still proceeding with all other discovery as to wholesalers, they're still getting the profit information from their target, all allegations of wrongdoing which are the manufacturers, and there is still time before any sort of trial or, I might add, class certification, so, to catch up, if by some miracle the unjust enrichment or disgorgement of profits survive as to the wholesaler

defendants.

We'll rely on -- to try to be concise, we'll rely on everything else that we have in the brief, and, of course, are happy to answer any questions, and are, of course, happy to apply all of these factual details as proven up in the declarations to the proportionality or good cause elements, as well, if the Court is interested in that. I think a lot of it is repetitious and I think a lot of it is sort of self-apparent from the argument that I just made, but I want to make sure we don't miss anything that your Honor is concerned about.

THE COURT: Thank you, counsel. You've been comprehensive.

How about the retailers, do you want to weigh in on this issue? Because am I wrong that, in effect, it's the same issue that the retailers are arguing about?

MS. JOHNSTON: Yes, your Honor. And I will be brief and try not to repeat too much of what Ms. Davis said. I think that most of what she articulated is applicable to the retailers in their role as a downstream --

THE COURT REPORTER: I'm sorry. Who's speaking?

MS. JOHNSTON: I'm sorry. This is Sarah Johnston.

THE COURT REPORTER: Thank you.

MS. JOHNSTON: Your Honor, I would say, you know, first off, that the questions that you ask I think are the

right questions, and they're the questions that we have as well, and to respond to those, I think it is telling that there are no cases cited in plaintiffs' briefing that would be applicable to a case like this, and we are talking about a true product liability context in which there is no allegation of wrongdoing as to these defendants. Because the remedies that plaintiffs are suggesting is the one that they are pursuing, is not the remedies that they will be entitled to once -- if and when this case ever gets to class certification as to the downstream defendants.

Secondly, the same question you asked is one that we've had, which is when we talked about this, quote, unquote, damages model this information is so important for, it's very unclear which plaintiffs we are talking about, and as to the retailers, and for the purposes of working up the economic loss class, we are only named as to the consumer class portion of that, and so the question you raise about, you know, are you entitled to the profits on a toaster is the same general question that we've had. If you truly are claiming that you are damaged by virtue of purchasing this allegedly contaminated drug, is your remedy truly the disgorgement of profits or is it payment for the out-of-pocket expense? And we would argue that it's the latter, because that is what makes sense in thinking conceptually about what the possible damages would be.

Third, you asked, you know, is -- are the different tiers of defendants interrelated, assuming that this is something that -- that plaintiffs are ordered -- or that defendants are ordered to produce to plaintiffs, and the answer to that is no. And I think that there is not a conceivable way that profits as to the manufacturers for purposes of this disgorgement argument would rely on the profit of the downstream defendants, because they don't, and, realistically, it's not -- it's not possible to conceive of how a manufacturer couldn't determine what its profits were without relying on a bunch of other entities in the supply chain. So I don't think that they are interrelated. I understand why plaintiff would want to argue that they are, but the -- it does not make sense from a very common sense perspective.

And then, finally, there is -- again, there is no allegation of wrongdoing that would make this discussion one that would be needed to have. And so, I echo the same questions. And then I also can't overlook the fact that when we're talking about this, in every discussion that we've had thus far about, you know, this damages model, and why it is that plaintiffs would need this information, the response is always because we need it, because it's relevant. And when pressed further, it's never -- it's never clear, one, why it's relevant, or, two, who it's relevant for, which makes it all

the more troubling that we've gone through this process and obtained 14 declarations that explain explicitly to the Court why there is such concern about having to produce it, and, in response, all we hear is, well, we should get it because we want it.

And then finally, as to Ms. Davis's last point, I agree, the Rule 12 issue is -- is and has been on the horizon and, you know, a number of the arguments that would be tied to this issue of whether or not disgorgement of profits are even available are directly tied to the issues that are going to be briefed on Rule 12. So the -- the idea of reaching this issue before the Rule 12 briefings are considered by the Court I think is a premature action, and while, you know, there are a number of reasons to say that this is an inappropriate theory of recovery, I think it also truly does highlight why this is something that can't be taken up by the Court until Judge Kugler has been able to review and reach a decision on this issue at the time of the Rule 12.

THE COURT: Thank you, counsel.

Plaintiffs, you have the last word.

MR. STANOCH: Thank you, Judge.

We've said in our letter multiple times, I'm not sure how many other ways we can say it, that to calculate ill-gotten gains, it's what you sold something for, say 10 bucks, minus what it cost, say 4, your profits are 6. Not

that I want it. That's how the math is done. That's what the case law shows is done.

These are valid claims, your Honor. These are valid methods of recovery. Plaintiffs will be prejudiced at class cert and later eventually at trial. They don't have the facts necessary to show on a classwide basis method for calculating damages under this theory.

They may argue, ultimately, that the theory might not be -- might not be selected or might not carry the day at trial, but that doesn't relieve me of my obligation as plaintiff to come forward with the model supported by the right data, and the only way to get the data is to get it from these defendants.

And none of them have said that they would stipulate not to oppose class cert on this basis, which we have invited them to do, which means then the only alternative to that is we have to seek the information.

THE COURT: Thank you.

Defendants, one last question. If the Court denies the requested discovery, can defendants rely on plaintiffs' failure to produce profit information as a basis to deny class certification? Ms. Davis, how about you?

(No response.)

THE COURT: You're not at a loss for words, are you? Ms. Davis, are you there?

MS. DAVIS: Sorry, your Honor. I was talking; I was on mute.

So, to clarify, the Court's question is, if the unjust enrichment claim were to survive 12(b)(6) against the wholesalers on the current pleadings, and a denial of this information continued beyond that point, what proposed subclass would -- is anyone anticipating that the defendants would come in and say, no, no, no, you don't have my profit information? The class certification at that point is going to be, we have a class of these people who used contaminated valsartan, and the fights that I'm envisioning are on clarifying that it has been to be somebody that can prove product identification and all these other damage issues that we've talked about, but I don't understand the implications or what is being suggested that inhibits a class argument or class certification just based on disgorgement of profits.

THE COURT: Ms. Johnston, do you want to weigh in?

MS. JOHNSTON: Yes, your Honor.

I think that the argument we would make is really that the idea that disgorgement of profits as a damages model in the first place would be appropriate, and for all the reasons we've discussed and mentioned in our briefing, we don't think that that is, for a number of reasons. But it's also truly difficult for us to weigh that question without plaintiffs having specifically articulated how this damage

model would even work as to the downstream defendants because the remedy suggested by it is not an available remedy.

THE COURT: Okay. Thank you, counsel.

The record is closed on these discovery disputes.

What I'd like to do at this point, if I can ask your indulgence, is if you have no objection, to take a short break -- we've been at this for two hours -- reconvene at 4:00. We can call back in. And I'll read you the Court's opinion and order into the record. Will everyone be available and, most importantly, Carol, are you available?

THE COURT REPORTER: Yes, your Honor.

MS. DAVIS: Yes, your Honor.

MR. SLATER: Of course, Judge.

MR. STANOCH: Yes, your Honor.

THE COURT: So we'll adjourn for a little less than 30 minutes, reconvene at 4:00, and then you'll get the Court's ruling. We will see you in a few minutes, counsel. Thank you very much.

(A recess was taken from 3:35 p.m. to 4:00 p.m.)

THE COURT: Okay. We're back on the record in the Valsartan matter. This is Judge Schneider.

I'm going to read into the record the Court's oral opinion regarding the macro discovery disputes involved with the wholesaler and retailer defendants, to be confirmed in a Court order to be entered.

This matter is before the Court on what the Court has called macro discovery disputes between the plaintiffs and the wholesaler and retailer/pharmacy groups of defendants.

The Court heard oral argument this date, July 6, 2020, via conference call. As will be discussed in more detail, the discovery disputes generally relate to plaintiffs' requests for tracking, pricing, profit, and sales information from the wholesalers and retailers. This will serve as the Court's oral opinion, to be confirmed in an Order to be entered.

The parties are obviously familiar with the background of this matter, so only a brief summary will be provided.

This MDL involves the sale and consumption of allegedly contaminated valsartan blood pressure prescription medication. Three general master complaints have been filed: one, a proposed nationwide class action seeking economic damages on behalf of third-party payors; two, a proposed nationwide class action requesting medical monitoring relief; and three, a master complaint alleging consumers contracted various forms of cancer from ingesting valsartan contaminated with cancer-causing chemicals.

In excess of 300 separate bodily injury complaints have been filed to date, and recently approximately 30 new complaints are being filed per month.

Plaintiffs have sued various groups of defendants in the valsartan supply chain, starting with the foreign manufacturers of the active pharmaceutical ingredient, then proceeding to the finished dose manufacturers, then the so-called downstream defendants, which are the wholesalers and the retailers.

The API and finished dose manufacturer defendants have been and will be collectively referred to as "the manufacturing defendants."

The three wholesalers in the case are the major wholesale players in the distribution chain who comprise the majority of the wholesale market. These wholesalers are McKesson, Cardinal Health, and AmerisourceBergen.

The retail defendants are familiar names in the business such as CVS, Rite Aid, Walgreens, Walmart, et cetera.

To date, the parties' discovery efforts have focused on plaintiffs and the manufacturer defendants, and these defendants are in the process of responding to requests for production approved by the Court.

Since the discovery directed to the manufacturing defendants is well underway, it is now time to turn to the downstream defendants. Although these defendants vigorously deny any liability in the case, there is no doubt they possess some relevant and discoverable information to which plaintiffs are entitled. To a large extent, plaintiffs and the

downstream defendants have been able to resolve their disputes, which are reflected in the red-line version of plaintiffs' proposed requests for production attached as Exhibits B and C to plaintiffs' April 13, 2020, letter brief, Docket Number 413.

The remaining disputes are the subject of this oral opinion.

Insofar as the procedural history of the case is concerned, until just recently, the Court has barred motions to dismiss. Nevertheless, defendants' motions to dismiss will soon be filed and heard, to be followed in short order at an unknown future date by motions for class certification.

In the meantime, discovery is proceeding and the manufacturing defendants' ESI document production will be completed in the fall, with fulsome rolling productions between now and then.

The Court anticipates depositions will start in the late fall, but no later than December or January.

Starting with the wholesaler defendants, the parties dispute the extent of the upstream and downstream purchasing, sales, and pricing discovery that must be produced. As to the wholesalers' purchases and sales, in general fashion, plaintiffs want to know the details of the wholesalers' purchases of valsartan-containing drugs from defendant manufacturers from January 1, 2012, to December 31, 2019.

Plaintiffs want the same information for the same time period for the wholesalers' sales to defendant retailers.

As to pricing, plaintiffs want the financial details of each of the wholesalers' purchases and sales of valsartan-containing drugs during the designated time period.

The Court will first address plaintiffs' request for purchasing and sales discovery from the wholesaler defendants which has been referred to as tracing discovery. As to this nonfinancial discovery, plaintiffs argue the discovery is relevant to tracking the supply chain of the valsartan-containing drugs plaintiffs consumed and/or paid for. Plaintiffs argue the discovery is critical to knowing, in plaintiffs' words, who sold what and to whom. Plaintiffs maintain the requested discovery is helpful to showing which manufacturer defendants' valsartan-containing drugs made it into plaintiffs' hands and will enable plaintiffs to track what valsartan the wholesaler defendants purchased and, in turn, to whom they sold the valsartan. The Court refers to this as tracing or tracking discovery.

The wholesaler defendants object to plaintiffs' request for tracking or tracing discovery on various grounds, including the following: one, the requested discovery is not relevant; two, the requested discovery is not genuinely needed since it is duplicative of discovery to be produced by other defendants; three, the claims that plaintiffs need the

discovery for are futile; four, the requested discovery is highly proprietary and trade secret; and five, the requested discovery is disproportionate to the needs of the case and unduly burdensome to produce.

The most important question the Court must decide in this context regarding plaintiffs' request for purchasing and sales discovery from the wholesaler defendants or, in the Court's words, tracing discovery, is whether the requested discovery is relevant. If the answer is no, plaintiffs do not get any. If the answer is yes, the Court must address defendants' other arguments for why the requested discovery should not be produced.

Having considered the total record produced by the parties, including the declaration submitted by plaintiffs' data analytical consulting expert and the declarations submitted by the three wholesaler defendants, the Court finds that the requested discovery is plainly relevant to core issues in the case. It is unquestionably the case that a critical issue in the litigation is and will be whether plaintiffs consumed defendants' contaminated valsartan. The requested discovery asking for the details of the wholesalers' purchases and sales of valsartan-containing drugs is relevant to this issue.

The Court, of course, recognizes that the wholesalers have made a strong prima facie case that they do not track

their sales to retailers by lot numbers and that this is not required under the Drug Supply Chain and Security Act. However, the Court rejects the notion that if the wholesalers do not track sales by lot number, plaintiffs' requested discovery is irrelevant. The wholesalers ignore the fact that plaintiffs and their expert argue that even without the lot number, the wholesalers possess information relevant to tracking their sales. See generally the declaration submitted by plaintiffs' expert consultant, Paragraphs 11, 29, 36, and 46.

For example, in Paragraph 46, plaintiffs' expert concludes that given the extent of the data kept by the wholesalers, the wholesalers are able to identify how best to link their sales shipments to recalled lots.

See also Paragraph 29 where the expert states that even without a lot number, there are, quote, unquote, many ways to link a dispensed product to a lot.

In addition, in Paragraph 36, the expert states that the wholesalers have more than enough information in their inventory systems that could be used to associate lot numbers with the wholesalers' sales. Plaintiffs refer, for example, to DSCSA shipment labels, the wholesalers' inventory control systems, Advance Shipping Notices, T3 documents, and expiration dates.

The Court notes that the wholesalers spent most of

their brief arguing that they are not required to track sales by lot numbers. However, as plaintiffs argue, and the Court agrees, this does not mean the wholesaler defendants have no helpful tracing data. The wholesalers have the lot number provided by the manufacturers. They also know the NDC number, the manufacturer's name, quantities, dosage, and perhaps the expiration date. Plaintiffs are entitled to see for themselves if they can use this relevant data, combined with the information from the wholesalers' sophisticated inventory control systems, to trace plaintiffs' purchases.

The Court, of course, is not blind to the fact that the wholesalers vigorously contest plaintiffs' conclusions. Representative of the wholesalers' position is the declaration of Scott Mooney from McKesson. Apart from stating that the wholesalers are not required to track by lot number, Mooney concludes "no amount of discovery will allow plaintiffs to trace lots from the wholesaler defendants to retailer defendants and then into the individual plaintiff's hands." Paragraph 61.

He also concludes there is no way to find out the lots a specific retailer defendant received from a wholesaler. Paragraph 64.

At this stage of the case, however, the Court is not prepared to give conclusive binding effect to Mooney's statements. The wholesalers' conclusions have been disputed

by plaintiffs' qualified expert, and plaintiffs should have an opportunity to test and question the wholesalers' conclusions.

In this regard, plaintiffs' reply brief persuasively points out the wholesalers' representations concerning their inventory control systems are not entirely consistent with the averments in the wholesalers' declarations. Plaintiffs are entitled to know for themselves if the wholesalers' documents will enable them to trace plaintiffs' purchases. At this stage of the case, plaintiffs are entitled to find out for themselves if they can trace plaintiffs' purchases, with help from the wholesalers' documents. Plaintiffs are not now bound to accept the wholesalers' conclusions at face value, especially when they are contested by plaintiffs' expert.

Having found the requested tracing discovery is relevant to core issues in the case, the Court can quickly dispense with the wholesalers' other arguments for why plaintiffs' discovery should be denied:

(1) While some of the discovery the wholesalers will produce will overlap the manufacturers' and perhaps the retailers' discovery, the discovery is not duplicative. The wholesalers undoubtedly have internal documents that the manufacturers and retailers do not have, and vice versa. In order to assure plaintiffs have a complete production, the wholesalers must produce their own documents and ESI, even if there is some overlap with other groups of defendants'

documents and ESI.

(2) The wholesalers' futility arguments are premature. This Court's role is to decide if the requested discovery is relevant to claims and defenses in the complaint pursuant to Rule 26. This Court's role is not to decide defendants' motion to dismiss. If the Court denied discovery every time a defendant argued plaintiffs' claims were futile or that its motion to dismiss would be granted, then no discovery would be produced and cases would grind to a halt. This is plainly unacceptable.

(3) As to defendants' arguments that the requested discovery is highly proprietary and trade secret, this is not a good ground to deny plaintiffs' relevant core discovery. The wholesalers' concerns about protecting the distribution of their confidential information are adequately addressed by the provisions in the Discovery Confidentiality Order the parties negotiated and the Court entered.

(4) As to the wholesalers' proportionality and unduly burdensome argument, the Court finds that plaintiffs have not satisfied their burden to bar the requested discovery on this ground. The requested tracing document discovery is relevant to critical core issues in the case. On the other hand, the wholesalers have not made a persuasive case that the requested discovery is unduly burdensome or not reasonably accessible. Instead, the wholesalers merely present conclusory, general

statements that are not persuasive.

For example, Tara Abraham from McKesson says at Paragraph 47 of her declaration that it will "take a large amount of time at great expense" to respond to plaintiffs' discovery.

Brett Harrop, H-A-R-R-O-P, from McKesson, says it will be "burdensome, expensive, and time-consuming" to generate the report plaintiffs want. Paragraph 22.

Matthew Sample from AmerisourceBergen says, at Paragraph 15 of his declaration, that it would require a significant expenditure of time and effort and would be extremely burdensome to respond to plaintiffs' discovery.

These types of general and conclusory statements do not and will not serve to bar plaintiffs from obtaining relevant core discovery.

One last point in this regard. Tara Abraham from McKesson avers it would be burdensome to respond to plaintiffs' discovery since the company only has one person to prepare a sales report from its BHP system. This argument is, and, if made in the future, will be soundly rejected.

All parties in the case must devote sufficient resources to adequately and timely respond to legitimate discovery requests. The Court and litigants will not be held hostage if a party unilaterally decides to slow walk discovery.

The Court addressed the same issue in its decision in *Constantino v. Atlantic City*, 152 F. Supp. 3d 311, District of New Jersey 2015, where a police department argued it did not have to produce relevant discovery because of limited available staff to do photocopying.

The Court wrote in that case, "It is unacceptable for a defendant to avoid legitimate discovery because it does not devote reasonable resources to defending a case." *Id.* at page 328.

What the Court said in *Constantino* is equally applicable here.

In addition, the Court rejects defendants' request that plaintiffs share in the cost of producing the requested discovery. Far from being marginally relevant, as defendants' argue, the requested tracing discovery goes to issues at the heart of the case. Apart from this, the requested discovery is not unreasonable or unduly burdensome. Thus, defendants' request for cost sharing is denied.

The Court now turns to plaintiffs' request for sales and cost data from the wholesalers.

Plaintiffs want to know the gross and net prices paid for the valsartan the wholesalers bought and the gross and net prices they sold the valsartan to downstream purchasers. Plaintiffs argue this discovery is relevant to their disgorgement and unjust enrichment claims. They also argue

the discovery is relevant to motive and intent, which the Court completely discounts.

The wholesalers argue the requested discovery is irrelevant, would be unduly burdensome to produce, and involves extremely confidential and trade secret information.

As to this discovery request, the Court declines to decide at this time if the requested discovery is relevant within the meaning of Rule 26. Instead, the Court finds that since the requested discovery is not relevant to a core issue in the case, and the viability of plaintiffs' profit and disgorgement claims will be decided when the Court rules on defendants' motions to dismiss, there is no pressing need for the wholesaler defendants to produce the requested sales and profit information now. From the beginning of the case, the Court has said it wants the parties to focus on the core issues. For example, was defendants' valsartan contaminated? With what? How much? When did this occur? Did plaintiffs ingest contaminated valsartan? Plaintiffs' request for profit and sales discovery, while ultimately may be important and relevant, is not directed to these core issues. The Court, therefore, defers this discovery for a later time in the case. The Court and parties can revisit plaintiffs' request after defendants' motions to dismiss are decided.

Turning to the retailer defendants, it appears there are two main points of contention: One, these defendants

object to producing upstream cost data, i.e., what the retailers paid for their valsartan; and two, certain downstream pricing data, namely, what insurers paid to the pharmacies for valsartan.

The retailer defendants argue the requested discovery is not relevant to any valid claim against them and that the burden of producing the discovery is disproportionate to its importance.

Plaintiffs argue the requested cost discovery is relevant to their disgorgement and unjust enrichment claims. In addition, plaintiffs argue they need the requested discovery to determine these defendants' profits.

As to the second issue in dispute, what the third-party payors paid for valsartan, the retailers argue the requested discovery is irrelevant, since the TPPs have not asserted a claim against them, only the consumers.

In opposition, plaintiffs argue one filed case asserts a claim by a TPP against the retailers and plaintiffs may amend their master complaint. Plaintiffs also argue they need to know what the TPPs paid the retailer defendants in order to know how much these defendants made in sales. Plaintiffs argue they need to know how much the TPPs paid the retailers in order to calculate the damages recoverable from the other defendants.

As to this requested profit discovery, the Court

rules the same way it did when the discovery was requested from the wholesalers. To repeat, this discovery is not directed to the core issues in the case and will be the subject of defendants' motions to dismiss. Thus, the Court defers this discovery for a future date which, in all likelihood, will be after defendants' motions to dismiss are decided.

The Court notes that it sees absolutely no prejudice to plaintiffs from the deferral of the ruling on the relevance of the requested discovery. At the appropriate time, the Court can address the issue. And, if genuinely needed, whether to prove liability, class certification, or damages, the Court will address the issue. The Court is convinced that the parties can better spend their time, and the more productive use of the parties' time will be spent on focusing on core issues rather than the disgorgement of profits and unjust enrichment claims that will be the subject of motions to dismiss to be decided.

In sum, therefore, the Court will grant plaintiffs' request that the wholesalers have to respond to requests for production 1 and 3.

The Court will deny without prejudice plaintiffs' request that the wholesaler defendants respond to requests for production 2 and 4.

As to the retailers, the Court's ruling is the same

as the Court ruled with regard to requests for production 2 and 4.

The Court's order will also state that the final version of the wholesaler and retailer fact sheets shall be served by Thursday.

The Court's order will provide that the wholesalers and retailers have to respond within 30 days.

In addition, the Court will add to the order a provision or provisions that was in the order that the Court cited to from the *Androgel Antitrust Litigation*, 2012 Westlaw 12895205, Northern District of Georgia, March 29, 2012. In that case, the Court ordered the same three wholesalers to produce all purchase and sales data regarding certain drugs, essentially, the same or similar order to what this Court is doing, with two additional provisions which will be included in this order.

The wholesalers are ordered to provide a written description of the data and data fields that they supply; and the wholesaler defendants will be ordered to undertake reasonable efforts to address the plaintiffs' reasonable questions concerning the data that was -- that will be produced.

Counsel, that completes the Court's oral opinion. I don't anticipate that an order will be entered today, but you'll see the Court's order tomorrow or the day after.

While we're together, are there any other issues or matters we need to address?

MS. JOHNSTON: Yes, your Honor. This is Sarah Johnston for retailers. I just wanted to clarify a couple things I heard at the end of the oral order.

The first was that, as I heard it, I think you said that the final versions of the fact sheets would be served by Thursday, and I wanted to confirm if that was RFPs -- the Rule 34 requests and not the fact sheets.

THE COURT: You're absolutely right, Ms. Johnston. I misspoke. I was only referring to the requests for production.

MS. JOHNSTON: Okay. And then, also, I wanted to make sure that we were following the same process that was in place for the manufacturing defendants, that is, when you say serving those, are we filing those with the Court, with service to follow to defendants, or did you have a different process in mind?

THE COURT: Serve them on the Court on Thursday. I will enter an order approving the requests for production, indicating that they have to be answered within 30 days, with no objection. Just like we did with the manufacturers.

MS. JOHNSTON: Sure. And the -- oh, I'm sorry. Go ahead.

THE COURT: The reason the wholesalers and retailers

have 30 days to respond is because this discussion has gone on for, in the Court's view, respectfully, an unreasonable amount of time. I think that this whole process could have been advanced by months if there was exemplar or sample documents produced. They weren't produced. The Court didn't order them to be produced, although that was defendants' preference. So I'm not going to let that delay the progress of this case.

We had a hiccup in the case, understandably, due to the virus, perfectly reasonable, we closed things down, but it's time to start moving things, and that's why the Court is going to insist that they be responded to within 30 days.

MS. JOHNSTON: Understood, your Honor.

And because this is a general set of discovery, we had always contemplated that there were going to need to be individualized responses because certain data is kept by certain retailers and not by others, and so we understand that a written response clarifying what will ultimately be produced is warranted. But I do want to clarify that the Court is contemplating a written response within 30 days and not a full-scale document production.

THE COURT: No, that's not correct. The Court is anticipating a written response and a document production. The wholesalers and retailers have had these requests for months. They've been on notice of these requests. They have the resources to produce the documents. 30 days, response in

writing, no objections, with the responsive documents and ESI.

MS. JOHNSTON: Your Honor, I want to clarify the understanding in what we've discussed with plaintiffs has not contemplated that documents would be produced within 30 days, namely because we have repeated time and time again to plaintiffs that unless we have a discovery vehicle to prompt the collection, review, production of documents, it's not -- we don't have a timeline that is triggered by that.

I would propose that we can provide written responses and, again, rolling collections -- or rolling productions as soon as possible, but I don't think that it's -- it's feasible for the retailers to complete their production, particularly in light of the fact that, you know, while this has been a process that's been ongoing for the last several months, the -- the hiccup was a substantial business interruption for many of the retailers and other downstream defendants, such that the idea that we could get documents collected and produced in such a short order is more difficult than it has been in the past, and I would also say that, as the Court may remember, the hearing on the macro discovery issues was continued twice because of the difficulty with obtaining the necessary evidence to support our arguments, in light of the COVID pandemic, and so I would -- I would offer to the Court that the same difficulties still exist with these companies, and have existed for the last several months. So, you know,

assuming the understanding that documents were to be collected and produced while we were waiting for final discovery documents, you know, understanding that to be the Court's expectation, the reality is that the difficulty alone in finding declarants in order to put the evidence before the Court to support our macro briefing was a challenge in and of itself, and I don't think that the process of collecting documents either would have been easier during that period or is frankly going to be any less of a challenge now. So while I think that we can move forward and begin the process of getting these documents ready to produce, 30 days is going to put nearly all, if not all, of the retailers in a pretty dire position.

MS. DAVIS: Your Honor, D'Lesli Davis for wholesalers.

We would join in the retailers' concerns about that and would request sort of a 60-day period, at least, to begin what would be a good-faith rolling production.

THE COURT: Counsel, the Court said what it said. The order is going to state what the Court indicated, for the reasons that the Court already stated.

Respectfully, the Court has been overindulgent in accommodating interests in the case, pushed deadlines back. It is what it is.

In the Court's view, your clients have been on notice

for months about what was at issue. There was a small smidgeon of information that was the subject of this macro dispute. There is no reason they couldn't have pulled together whatever other information plaintiffs requested. Your clients decided not to produce samples or exemplars which would have advanced this process by months. That was its decision. We'll live with it.

I have nothing to add to the Court's explanation. The order is going to state 30 days to respond in writing and produce the responsive documents, with no objection.

Anything else, counsel, we need to address?

MS. DAVIS: Not from the wholesalers, your Honor.

THE COURT: I thank everyone for your excellent briefs and oral argument.

Like I said, I don't think you're going to get the Court's order today, but, hopefully, you'll get it tomorrow, and if not tomorrow, the day after. But I'll look for the final requests for production on Thursday, enter it, and then we'll turn our attention to finishing the other issues we need to finish. We need to finish, I guess, the manufacturers' fact sheets; we need to finish the fact sheets for the wholesalers and retailers. And then I think when we get that out of the way, you can focus on producing your documents and ESI, and then we'll turn to getting ready for the depositions in the case.

For the people on my team who are on the phone, can I ask you to call back to this number in ten minutes? There are certain issues I need to talk to you about.

Counsel, thank you very much. I appreciate your indulgence, this went pretty long, and we're adjourned.

(The proceedings concluded at 4:42 p.m.)

- - - - - - - - - - - - - - -

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Carol Farrell, NJ-CRCR, FCRR, RDR, CRR, RMR, CRC, CRI
Court Reporter/Transcriber

July 09, 2020
Date

B

C

D

G

H

I

J

K

L

T

U

V